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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/966,939 | 09/28/2001 | Harry S. Sowden | MCP-0242 | 5012 |

27777 7590 04/23/2003
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EXAMINER

DAVIS, ROBERT B

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1722

DATE MAILED: 04/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-13

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/966,939 | Applicant(s) SOWDEN ET AL. | |
| | Examiner Robert B. Davis | Art Unit 1722 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-45 is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,8,12</u> . | 6) <input type="checkbox"/> Other: BEST AVAILABLE COPY |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On line 27 of page 21, the serial number of co-pending application is blank.

A new copy of the specification and claims is required with the proper upper margins. The current copy of the specification has holes punched through the first line of each page.

Appropriate correction is required.

Election/Restrictions

2. Applicant's election without traverse of Group II, claims 34-45 in Paper No. 11 is acknowledged.

3. Claims 1-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Allowable Subject Matter

4. Claims 36-45 are allowed over the prior art of record.
5. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teach or suggest a linked apparatus for making dosage forms containing a medicant comprising: a compression module having means for forming compressed dosage forms by compressing a powder containing a medicant, a transfer device having means for continuously transferring said compressed dosage forms from the compression module to a thermal cycle molding module, and a thermal

Art Unit: 1722

cycle molding module having means for continuously molding a coating of flowable material over said compressed dosage forms. The means for forming a compressed dosage form by compressing a powder is a tableting press as is well known in the art. The means for continuously molding a coating of flowable material over the said compressed dosage forms is a number of female molds rotating about an axis such that a plurality of molds are in various stages of the injection molding process. Each of these molds has at least an inlet for the injected flowable material. None of the prior art of record teaches or suggests the apparatus of claim 44 as this claim presents the combination of a first and second rotor wherein the first rotor has a plurality of die cavities and at least one punch to compress powder material and the second rotor has a plurality of mold cavities capable of enclosing at least a portion of a compressed dosage form and capable of receiving a flowable material so as to coat a portion of the compressed dosage form. The claim also requires the transfer mechanism between the two rotors. The prior art does not teach the combination of a compression-molding tool to form a compressed dosage form and an injection-molding tool for encapsulating or forming a coating on a portion of the compressed dosage form in a mold. The prior art discloses various other devices for forming a multilayer dosage form. Berta (5,679,406) discloses a dipping apparatus for dipping a compressed form into two differently colored materials. Engel et al (WO 99/02136) discloses co-injection of two materials into a mold to form a multilayer article. Doepel et al (2,946,298) and Rudzki (3,096,248) disclose first and second compression steps to form a multilayer compression molded dosage form; however, these references do not teach or suggest a first compression mold and

Art Unit: 1722

then encapsulating or partial coating of a compressed tablet or dosage form with a flowable material in an injection mold.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The remaining references show various apparatus for forming tablets or dosage forms.

7. This application is in condition for allowance except for the following formal matters:

The blank serial number in the specification and the improper margin on every page of the specification and claims.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

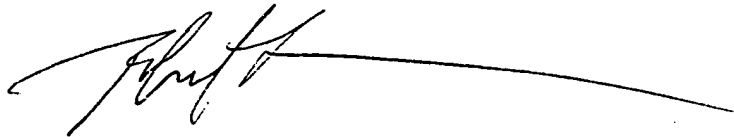
A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Davis whose telephone number is 703-308-2625. The examiner can normally be reached on Monday-Friday 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1722

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Robert B. Davis
Primary Examiner
Art Unit 1722

4/21/02

April 21, 2003